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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,559	07/26/2001	Juergen Roemisch	06478.1457	4592

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EXAMINER

CAPUTA, ANTHONY C

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 09/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/912,559

Applicant(s)

ROEMISCH ET AL.

Examiner

Brenda G. Brumback

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, drawn to polynucleotides encoding a mutant factor VII-activating protease (FSAP), classified in class 536, subclass 23.2.
- II. Claims 3-4, drawn to polypeptides comprising mutant FSAP, classified in class 435, subclass 219.
- III. Claims 5 and 27-28, drawn to diagnostic methods using a polynucleotide encoding a mutant FSAP, classified in class 435, subclass 6.
- IV. Claim 6, drawn to diagnostic methods using a mutant FSAP polypeptide, classified in class 435, subclass 7.6.
- V. Claims 7 and 16, drawn to antibodies directed against a mutant FSAP polypeptide, classified in class 530, subclass 387.1.
- VI. Claims 8-11, 17 (in part), 23-26, and 29, drawn to methods of detection of a mutant FSAP using an antibody, classified in class 435, subclass 7.1.
- VII. Claims 12-14, drawn to methods of making a mutant FSAP polypeptide, classified in class 435, subclass 69.1.
- VIII. Claim 15 (in part), drawn to methods of administering a mutant FSAP polypeptide for prophylactic or therapeutic inhibition of bleeding, classified in class 514, subclass 2.
- IX. Claim 15 (in part), drawn to methods of administering an antibody directed against a mutant FSAP polypeptide for prophylactic or therapeutic inhibition of bleeding, classified in class 424, subclass 146.1.

Art Unit: 1642

- X. Claim 15 (in part), drawn to methods of administering an antibody and polypeptide in combination for prophylactic or therapeutic inhibition of bleeding, classified in class 424, subclass 178.1.
- XI. Claim 17 (in part), drawn to methods of purification of a mutant FSAP polypeptide, classified in class 530, subclass 413.
- XII. Claim 17 (in part), drawn to methods for detecting antibodies against FSAP, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III and XII; II and IV and VII; and V and VI and IX and XI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group I can be used in the materially different process of gene therapy, as well as in protein production and as diagnostics; the polypeptides of Group II can be used in the materially different processes of affinity purification of antibodies, as well as for therapy and as diagnostics; and the antibodies of Group V can be used in the materially different processes of affinity purification of proteins, as diagnostics, and as therapeutics.

The products of Inventions I, II, and V have different structures, different chemical compositions, are used for different purposes, and have different immunological characteristics.

The methods of Inventions III, IV, and VI-XII utilize different components, are for different purposes, and have different outcomes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Art Unit: 1642

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Official FAX telephone number is (703) 872-9306 and the After Final FAX telephone number is (703) 872-9307. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

BB

September 19, 2002



Brenda Brumback
Supervisory Patent Examiner
Technology Center 1600